Attorney Docket No.: PTQ-0037
Inventors: Van Eyk et al.
Serial No.: 09/934,297
Filing Date: August 21, 2001
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REMARKS/ARGUMENTS

Claims 1-56 are pending in the instant application.

Claims 9-28 have been withdrawn from consideration by the Examiner and subsequently canceled without prejudice by Applicants in this amendment. Please see the attached request for Correction of Inventorship in this patent application resulting from cancellation of these claims.

Claims 1-8 and 29-56 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

I. Finality of Restriction Requirement

The Examiner has made final the Restriction Requirement mailed September 29, 2003.

Applicants respectfully request that the record be clarified that election in the December 1, 2003 response by Applicants was made **with traverse** as there is some confusion with respect to the traversal in page 2 of the instant Office Action.

In light of the finality of this Restriction Requirement, Applicants have canceled without prejudice non-elected claims 9-28. Applicant reserve the right to pursue this subject matter in a divisional application.

II. Rejection of Claims under 35 U.S.C. § 103

Claims 1, 2, 5, 8, 33, 34, 35, 37, 38, 42, 45, 48, 49, 50, 51, 53 and 54 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Figard (U.S. Patent 5,616,460) in view of Pilotti et al. (U.S. Patent 5,994,507).

Claims 3, 4, 7, 29, 30-32, 36, 39, 40, 41, 43 and 44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Figard (U.S. Patent 5,616,460), in view of Pilotti et al. (U.S. Patent 5,994,507), as applied to claim 1, and further in view of Schwartz et al. (U.S. Patent 6,020,139).

Claims 6, 46, 47, 55 and 56 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Figard (U.S. Patent 5,616,460), in view of Pilotti et al. (U.S. Patent 5,994,507), as applied to claim 1, and further in view of Rubenstein et al. (U.S. Patent 4,376,825).

Claim 52 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Figard (U.S. Patent 5,616,460), in view of Pilotti et al. (U.S. Patent 5,994,507), as applied to claim 1, and further in view of Aitman et al. (U.S. Patent 6,322,976).

Applicants respectfully traverse these rejections.

The primary reference cited in all of these rejections under 35 U.S.C. § 103 is Figard (U.S. Patent 5,616,460). It is

respectfully pointed out that the Examiner's characterization of the teachings of Figard is flawed.

The Examiner suggests that Figard discloses the invention substantially as claimed. More specifically, the Examiner suggests that Figard discloses a method of separating a mixture of proteins in a biological sample (col. 5, lines 6-9 and 13-15) comprising:

(a) substantially denaturing protein in said sample (col. 5, lines 6-9, 13-15 and 31-35) . . .

Applicants respectfully disagree.

Figard discloses an immunoassay buffer for stabilizing antigens and preventing non-specific binding of non-analyte antibodies to a solid phase. Thus, the focus of Figard is to avoid denaturing conditions since such conditions could potentially denature the antigen of interest or the corresponding antibody. Portions of column 5 relied upon by the Examiner to suggest that this reference teaches substantially denaturing protein in a sample have nothing to do with denaturing conditions, but rather relate to reduction of non-specific binding. In fact, column 5 of Figard does not even contain the word "denature" or denaturing". Further, the composition taught by Figard is not a denaturing composition. Instead, the

composition taught by Figard uses DTT, to keep the sample reduced, and ethylene glycol, to prevent DTT from oxidation (see col. 2, lines 39-43 and col. 4 lines 33-67). While Figard teaches that the composition may optionally include a detergent, at col. 5, lines 28-31, Figard teaches that preferably a detergent is used because they are known to reduce non-specific binding while simultaneously not inhibiting binding.

Thus, Figard does not teach or suggest denaturing protein in said sample as required in the instant invention.

Further, teachings of secondary references fail to remedy the deficiencies in this primary reference.

Pilotti is also cited by the Examiner in each of the above rejections and is acknowledged by the Examiner to teach a method for removing albumin from liquid samples for purifying albumin and processing the samples in the absence of albumin. The Examiner suggests that because Pilotti et al. teaches non-specific binding of albumin through hydrophic interactions, it would have been obvious to modify the method of Figard to reduce non-specific binding of albumin as taught by Pilotti et al. No where, however, does Pilotti et al. teach or suggest denaturing protein in said sample as required in the instant invention.

Schwartz, cited against dependent claims 3, 4, 7, 29, 30-32,

36, 39, 40, 41, 43 and 44 for its teachings of diagnostic assays for detection of disease states and conditions; Rubenstein, cited against dependent claims 6, 46, 47, 55 and 56 for its teachings of assays involving blood proteins found in blood; and Aitman et al., cited against dependent claim 52 for its teachings of assays involving antibodies wherein the non-ionic detergent Ipegal-360 is used, also provide no teaching or suggestion of denaturing protein in said sample as required in the instant invention

MPEP § 2143 states that to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations.

The cited combination of prior art, which contains no teaching or suggestion of denaturing proteins, clearly fails to teach or suggest all the limitations of the instant claims wherein step (a) of independent claim 1 (from which all other claims ultimately depend) states "substantially denaturing albumin in said biological fluid sample . . ." Further, the

cited combination of references provides no reasonable expectation of success with respect to the invention of claim 1, since again, there is no teaching or suggestion of substantially denaturing protein in the sample as required in the instant invention. And finally, there is no motivation to combine the primary reference of Figard with a reference teaching denaturing of protein in the sample since the focus of Figard is to avoid denaturing conditions which could potentially denature the antigen of interest or the corresponding antibody.

Thus, the cited combination of references fails to meet the basic criteria required to establish a prima facie case of obvious with respect to independent claim 1. Further, MPEP § 2143.03 states that when an independent claim is nonobvious under 35 U.S.C. § 103, any claims depending therefrom are also nonobvious. Thus, dependent claims 2-8 and 29-56 must also be nonobvious.

Withdrawal of these rejections under 35 U.S.C. § 103(a) is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending

claims is earnestly solicited.

Respectfully submitted,

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Date: July 26, 2004

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